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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,049	06/02/2000	KAZUHIKO AMANO	P2292.D1	6603

20178 7590 08/08/2003

EPSON RESEARCH AND DEVELOPMENT INC  
INTELLECTUAL PROPERTY DEPT  
150 RIVER OAKS PARKWAY, SUITE 225  
SAN JOSE, CA 95134

[REDACTED] EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 08/08/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/587,049	AMANO ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Robert L. Nasser	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 May 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 7-30,33,36 and 38-43 is/are pending in the application.
  - 4a) Of the above claim(s) 26-30 is/are withdrawn from consideration.
- 5) Claim(s) 8-12,15,18,20,39,40 and 43 is/are allowed.
- 6) Claim(s) 7, 13, 14, 16, 17, 19, 21-24, 33, 36, 38, 41, and 42 is/are rejected.
- 7) Claim(s) 25 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

Art Unit: 3736

Claims 26-30 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 13.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 14, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Merki et al. In column 4, under the heading blood pressure, Merki teaches a device including a means to measure an indicator of a physiological state. The examiner notes that the structure corresponding to the means in Amano is a pulse wave detector. It is the examiner's position that the intra-arterial pressure sensor disclosed by Merki is equivalent to the pulse wave detector, as both output a signal indicative of the blood pressure variations over time. Merki further has means to store the values of blood pressure 10, means for processing the blood pressure signals and comparing the values to reference values for a period of time, and outputting a drug emission command based off of the variation in pressure over time. The administration means is an infuser of the drug. Again, it is the examiner's position that the infuser of Merki is equivalent to the disclosed infuser of applicant.

Claims 13, 16, 33, 36, 41, and 42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Koyama et al. Specifically Koyama monitors the pulse rate with a pulse wave sensor 11, determines the rhythm of variation of the pulse rate over a period

Art Unit: 3736

of time with computing means 19, and administers a fragrance when the patient is indicated to be in a state of sedation.

Claim 33 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cosgrove Jr. et al, see column 5, lines 1-13, discussing using a combination of EEG and blood pressure to trigger administration of drugs.

Claims 36 and 38 are rejected under 35 U.S.C. 103(a) as being obvious over McNally et al. McNally teaches a system that has a sensor to monitor a parameter indicative of arousal or sedation (blood pressure) and produce a signal, means to processing the signal to control a drug delivery device to deliver a drug to the patient, by comparing the current signal with a stored parameter indicative of the desired state and either sedate the patient when the signal indicates arousal or arouse the patient when the signal indicates sedation. The drug delivery device is an infuser. The examiner notes that McNally administers two separate drugs, hypotensive and hypertensive agents. Whether one device controls both drugs, or each has a separate control would have been obvious to one skilled in the art.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merki et al in view of Langen et al. Merki et al shows the features of the claims, except for the communicating and receiving data from an external device. Merki et al sends data to an

Art Unit: 3736

external device through element 14. Langen et al shows a device for monitoring patient condition, which sends and receives data from a central computer when data is abnormal. As discussed in the reference, it allows for broader access to the physician and eliminates the need for repeated office visits. Hence, it would have been obvious to modify Merki et al to receive data back from a physician, as it provides broader access to healthcare.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merki et al in view of Koyama et al. Koyama et al bases the drug administration command off of a moving average. As such, anomalous signals are discounted in the measurement and the measurement is tuned to the patient's specific body. Hence, it would have been obvious to modify Merki to use a moving average, so as to eliminate anomalous data and tune the device to the particular patient.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merki et al in view of Valcke et al. Valcke further teaches sounding an alarm when the total amount of the drug administered reaches a set amount, to prevent over dosing the patient. Hence, it would have been obvious to modify Amano et al to include such an alarm , to prevent injury to the patient.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merki et al in view of Valcke et al as applied to claim 21 above, and further in view of Coutre et al. Coutre et al further teaches monitoring the operating condition of a drug infusion system and sounding alarms when the system is not operating correctly.

Hence, it would have been obvious to modify Amano et al to use such a system monitor, to ensure proper system operation and proper patient treatment.

Claims 8-12, 15, 18, 20, 39, 40, and 43 are allowable.

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 8 defines over the art of record in that none of the art measures both a parameter indicative of arousal or sedation and a blood pulse wave, and compares the waveform to a reference waveform to trigger the administration of a drug, as claimed. The art of record compares a value to a reference value or an average, but not a pulse waveform to a reference pulse waveform. Claims 9, 10, and 39 define over the art in that none of the art shows the means for detecting, as claimed. Claims 11, 12, 25, and 40 define over the art in that none of the art shows a device that varies administers a drug from one beat to another in synchronization with the pulse, as claimed. Claim 15 defines over the art in that none of the art shows the control means function recited in the last paragraph. Claim 18 defines over the art of record in that none of the art shows the control means function recited in the last paragraph. Claims 20 and 43 define over the art of record in that none of art of record shows the means for detecting in the last paragraph.

Applicant's arguments filed 5/23/2003 have been fully considered but they are not persuasive.

With respect to Cosgrove Jr. and McNally, applicant has asserted that those reference do not emit a drug, because they have an infuser and an injection device. The examiner notes that the first of the definitions in Webster's New World Dictionary, Third College Edition of emit is discharge. Therefore, these devices emit a drug. Applicant appears to be trying to distinguish between emitting an airborne fragrance and injecting or infusing a drug into the body. However, applicant should amend the claims to more clearly bring out the distinction.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sherer et al and Sramek show devices that control the administration of a drug based off blood pressure. .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Application/Control Number: 09/587,049  
Art Unit: 3736

Page 7

Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN  
August 7, 2003

*Robert L. Nasser Jr.*

ROBERT L. NASSER  
PRIMARY EXAMINER